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510(k) Summary

Submitters Name and Address: ReNu Medical, Inc.
9800 Evergreen Way
Everett, WA 98024
Phone: 425-353-1110
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JAN 14 2010

FDA Registration Number: 3034520

Contact Person: L. Bruce Pierson
Chief Operating Officer

Date Summary Prepared: 01/06/10

Trade or Proprietary Name(s): ReNu Medical Reprocessed Vaso Press CTC calf, thigh and foot DVT garments. (All sizes)

Common Name: Sleeve, limb, compression

Product Code: JOW

Panel: Cardiovascular 870.5800

Classification: Class II

Equivalent Device(s)

The ReNu Medical Reprocessed ALP DVT garments. 510k# K051227
ReNu Medical Reprocessed many different manufacturers types/sizes DVT garments 510k# K031159

Device Description:

The ReNu Medical Reprocessed Vaso Press CTC calf, thigh and foot DVT garments. (All sizes)

Indications for Use:

The ReNu Medical Reprocessed Vaso Press CTS Calf, Thigh and foot DVT garments are to be used by patients in both the home and institutional settings as a non-invasive therapeutic method to prevent deep vein thrombosis and resulting pulmonary embolism.

Technological characteristics of the ReNu Medical Reprocessed Vaso Press CTC DVT garments:

The predicate devices and the ReNu Medical Vaso Press CTC DVT garments are identical in intended use, fundamental scientific technology, overall design, materials, energy source, mode of operation, performance techniques and reprocessing methodology.

Summary of Comparison Tests
Bench testing was conducted to ensure that reprocessing did not compromise the performance of the device in a manner that is substantially equivalent to that of the predicate devices.

Biocompatibility

Reprocessing does not affect the biocompatibility of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

JAN 14 2010

ReNu Medical, Inc.
c/o Mr. Bruce Pierson, COO
9800 Evergreen Way
Everett, WA 98204

Re: K093658
ReNu Medical Reprocessed Vaso Press CTC Calf, Thigh and Foot DVT garments. (ALL Sizes)
Regulation Number: 21 CFR §870.5800
Regulation Name: Sleeve, Limb, Compressible
Regulatory Class: Class II
Product Code: JOW
Dated: November 20, 2009
Received: November 25, 2009

Dear Mr. Pierson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K093658

Indications for Use

510(k) Number (if known): K093658

Device Name: ReNu Medical Reprocessed Vaso Press CTC Calf, Thigh and Foot DVT garments. (All Sizes)

Indications for Use:

The ReNu Medical Reprocessed Vaso Press CTC calf, thigh and foot DVT garments are to be used by patients in both the home and institutional settings as a non-invasive therapeutic method to prevent deep vien thrombosis and resulting pulmonary embolism.

Prescription Use XX AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R Vichman

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K093658